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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/530,052 | 08/04/2005 | Philippe Chenevier | 1017753-000205 | 5521 |

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| EXAMINER | |
|---|---|
| YOUNG, MICAH PAUL | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1618 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 10/23/2009 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/530,052 | CHENEVIER ET AL. | |
| | Examiner | Art Unit | |
| | MICAH-PAUL YOUNG | 1618 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *22 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

**Acknowledgment of Papers Received:** Amendment/Response dated 6/22/09.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Chen et al (USPN 6,544,556 hereafter '556) in view of Criere (FR 2,793,688 hereafter '688).

The '556 patent teaches a pharmaceutical formulation comprising a spheroid core wherein the core comprises an active agent such as an NSAID and a proton pump inhibitor such as omeprazole (col. 5, lin. 35-col. 7, lin. 15, Example 2). The spheroid core has an enteric coating directly applied to it (col. 4, lin. 4-15), where the coating comprises enteric polymers such as hydroxypropylcellulose phthalate, shellac and methacrylic acids along with plasticizers such as polyethylene glycol, along with surfactants like polysorbates (col. 10, lin. 10-25). The

core comprises binders such as polyvinylpyrrolidone starches and sugars (col. 8, lin. 60-68). The core further comprises lubricants, and diluents (col. 9, lin. 15-30). The enteric coated spheroids are further coated with an outer coating comprises water soluble polymers such as sugars, polyvinylpyrrolidone and carboxymethylcellulose (col. 10, lin. 30-40). The spheroids are prepared by first making the core and the applying the successive coating compositions in a fluidized bed device (col. 14, lin. 9-16). The spheroids are collected together and formed into tablets comprises a low concentration of excipients (Example 2). Although the reference discloses an enteric coating formulation mixed with other coating polymers they are silent to the specific components of the instant claims. The specific combination is described in the '688 patent.

The '688 patent discloses a control release formulation comprising granules coated with a mixture of an enteric polymer and a fatty acid (abstract). The granules are coated with a mixture comprising Eudragit polymers and Gelucire polymers (having a majority of palmitostearic acid having a melting point from 46-51 degrees Celsius and an HLB of 13 (page 12, lin. 20-26). It would have been obvious to coat the core particles of the '556 patent with the coatings of the '688 in order to provide more precise gastrointestinal delivery. Further the combination of the enteric polymer and the fatty acid polymer would have improved the shelf stability of the '556 patent since the coating of the '688 patent provides a prolonged shelf life.

Regarding the direct compressible and the future tablet comprising multiple spheroids, it is the position of the Examiner that such a limitation is merely a future intended use limitation. The proposed combination provides a structurally complete composition comprising a core, direct coating and a successive water dispersible coating. The '556 patent provides an inert seed

core that is combined with the same active principles as the instant claims as well as the same excipients (diluents, disintegrants, etc.). The drug coated pellet is then coated with an enteric polymer and further disintegrants, identical to the instant claims. The reference, though disclosing plasticizers and other polymers present in the enteric coating, is silent to the inclusion of the specific mixture of saturated and/or unsaturated polyglycosylated glycerides whose fatty acids contain at least 8 carbon atoms. The '688 patent provides a coated drug formulation where the coating formulation comprises an enteric polymer (Eudragit L30D a preferred polymer of the instant invention) and a mixture of saturated and/or unsaturated polyglycosylated glycerides whose fatty acids contain at least 8 carbon atoms, specifically Gelucire 15/30, the identical polymer preferred by the instant invention. The combination of the Eudragit and Gelucire polymers improves storage capabilities for the formulation and it would have been obvious to include the polymer combination to impart this improvement to the '556 patent as well. In combination this provides a structurally identical spheroid as the instant claims, and as such the claim preamble and future intended uses of the limitation do not impart patentability. The '556 paten clearly discloses multiparticulate tablets comprising the spheroids and auxiliary substances. These tablets are directly tabletted and would meet the limitations of the instant claims. Where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation. See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997).

With these aspects in mind it would have been obvious to include the polymers of the '688 patent into the coating compositions of the '556 patent in order to improve the absorption of

the active agents being coated. One of ordinary skill in the art would have been motivated to do so since both patents teach that these coating polymers can be applied directly to the drug containing core and discloses similar coating compositions. It would have been obvious to combine the teachings and suggestions as such with an expected result of stable core formulation useful in direct tableting with improved drug absorption properties.

***Response to Arguments***

Applicant's arguments filed 6/22/09 have been fully considered but they are not persuasive. Applicant argues that:

**The combination of the 556 and '688 patents does not obviate the instant claims since the combination does not teach or suggest spheroids that are directly compressible.**

Regarding this argument, it remains the position of the Examiner that the combination would continue to obviate the instant claims. First regarding the 'directly tabletable' and limitations regarding future intended tablets, it is the position of the Examiner that such limitations are merely a future intended use that do not distinguish the instantly claimed spheroids over the art. Where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation. See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997). In the instant case, the '556 patent provides an inert seed core that is combined with the same active principles as the instant claims as well as the same excipients (diluents, disintegrants, etc.). The drug coated pellet is then coated with an enteric polymer and further disintegrants, identical to the instant claims. The reference, though disclosing plasticizers and other polymers present in the enteric coating, is silent to the inclusion of the specific mixture

of saturated and/or unsaturated polyglycosylated glycerides whose fatty acids contain at least 8 carbon atoms. The '688 patent provides a coated drug formulation where the coating formulation comprises an enteric polymer (Eudragit L30D a preferred polymer of the instant invention) and a mixture of saturated and/or unsaturated polyglycosylated glycerides whose fatty acids contain at least 8 carbon atoms, specifically Gelucire 15/30, the identical polymer preferred by the instant invention. The combination of the Eudragit and Gelucire polymers improves storage capabilities for the formulation and it would have been obvious to include the polymer combination to impart this improvement to the '556 patent as well. In combination this provides a structurally identical spheroid as the instant claims, and as such the claim preamble and future intended uses of the limitation do not impart patentability. The '556 paten clearly discloses multiparticulate tablets comprising the spheroids and auxiliary substances. These tablets are directly tabletted and would meet the limitations of the instant claims. Applicant argues that the NSAID granules of the '556 patent would somehow render the '556 patent non-obviating. However the instant claims are drawn only to a spheroid, which is disclosed by the '556 patent throughout the specification and specifically at Table 6 and 7. The '688 patent provides the specific enteric coating formulation with improved stability. Applicant argues that the coating of the '68 patent is not applicable since the a drug is present in the coating and the coating is not applied to spheroids, but to granules that are filled into capsules and not formed into tablets. Applicant is reminded that the '688 patent is applied as a secondary reference and need not discloses each and every claim limitation in an of itself. The '688 patent is used to simply establish the level of skill in the art regarding the combination of enteric polymers and mixtures of saturated and/or unsaturated polyglycosylated glycerides whose fatty acids contain at least 8 carbon atoms. The '688 patent

establishes that the combination of these polymers is known in the art and has advantages and improvements. For these reasons the claims remain obviated.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618